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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,717	07/25/2003	Scott E. Andersen	38-21(15878)D	2211

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EXAMINER	
SITTON, JEHANNE SOUAYA	
ART UNIT	PAPER NUMBER
1634	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/626,717	ANDERSEN ET AL.	
	Examiner	Art Unit	
	Jehanne S. Sitton	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,6-12 and 14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4, 6-12 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10-2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Currently, claims 1-2, 4, 6-12 and newly added claim 14 are pending in the instant application. All the amendments and arguments have been thoroughly reviewed but are deemed insufficient to place this application in condition for allowance. The following rejections are either newly applied, as necessitated by amendment or are reiterated. They constitute the complete set being presently applied to the instant Application. Response to Applicant's arguments follow. This action is Non-FINAL.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The rejections under 35 USC 102 made in the previous office action are moot in view of the cancellation of claim 13.

Claim Rejections - 35 USC § 101

4. Claims 1-2, 4, 6-12 and 14 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility.

The claims are drawn to a substantially purified nucleic acid molecule comprising SEQ ID NO: 11 (claim 1), which encodes a wheat protein or fragment thereof (claim 2), or a protein or protein fragment that is at least 30 amino acids long (claim 14), as well as sequences having between 90%, 95%, 98%, 99% and 100% sequence identity with the entire length of SEQ ID NO: 11 (claims 4, 9-12). The claims are also drawn to a substantially purified nucleic acid

molecule comprising (claim 6) or consisting (claim 7) of a fragment of about 50 to about 100 residues wherein the fragment exhibits complete complementary to a sequence of SEQ ID NO: 11, the complements thereof, as well as such molecules which comprises a region having a single nucleotide polymorphism (claim 8). Claims 1, 2, 7 and 14 do not allow for internal variations within SEQ ID NO: 11. Claims 4, 6, 8, and 9-12 allow for internal variations. Such claims further encompass mutants, variants, and homologs from any plant or any wheat plant (claim 2), of genes, full open reading frames, fusion constructs and cDNAs.

The specification teaches that the claimed nucleic acid is an EST isolated from a wheat cDNA library. The claimed invention is not supported by a specific utility because the disclosed uses of the polynucleotide are not specific and are generally applicable to any EST. The specification discloses many potential uses for the polynucleotide including use as molecular tags to isolate genetic regions, isolate genes, map genes and determine gene function (page 13), to determine if genes are members of a particular gene family, to obtain full length genes (page 14), to isolate promoters and flanking sequences (page 32), for use in marker assisted breeding programs, to hybridize to its complement, to encode proteins, to obtain molecules from other plants (page 30), and to determine whether a plant contains a mutation (page 32). These are non-specific uses that are applicable in general to polynucleotides isolated from wheat and not particular or specific to the polynucleotide claimed.

Further, the claimed polynucleotide is not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. For

example, the specification teaches that the claimed nucleic acids can be used to identify a polymorphism. However, this is not considered to be a specific and substantial utility. The utility is not specific because it is a property of all wheat plant nucleic acids that they could be used to search for and try to identify a polymorphism. Further, the asserted utility is not substantial because it is a utility that is performed only to accomplish additional research. All discussions regarding polymorphisms in the specification are generic in nature. The specification does not teach any particular polymorphisms in SEQ ID NO: 11. The specification does not disclose an association between any particular polymorphisms and any phenotypic trait. The specification provides no indication as to what the nucleic acids are markers for. Polymorphisms are naturally occurring variations within sequences, which themselves may not have any meaningful use. To determine whether a nucleic acid contains a polymorphism would first require comparing the sequence of SEQ ID NO: 11 to other newly isolated nucleic acids. Then, upon identifying a nucleic acid variation, one would need to determine whether such a variation had any meaningful use – e.g., whether the variation was associated with a particular trait or characteristic of a particular strain of wheat plant. Therefore, the nucleic acids of SEQ ID NO: 11 may only be used to search for polymorphisms and if such polymorphisms are identified then the functional/biological activities of the polymorphisms could potentially be elucidated. Such research projects do not constitute a "real-world" use in currently available form.

As with the use of a nucleic acid to detect polymorphisms, a substantial utility for the nucleic acid can only be elucidated once the function of the nucleic acid or the product encoded by the nucleic acid is determined. The present specification does not teach a specific functional or biological activity associated with the nucleic acid of SEQ ID NO: 11 or a protein encoded by

SEQ ID NO: 11. SEQ ID NO: 11 may be a portion of a full length open reading frame, but the specification does not teach which protein is actually encoded by SEQ ID NO: 11. For example, it is not clear if nucleotide number 1 is the first nucleotide in a codon, or the last. The specification does not teach an association between the claimed nucleic acids and any particular condition in plants. In the absence of such information, the skilled artisan would not know how to interpret the results of methods which determine the expression of an mRNA or protein and would not know how to use a plant that was transformed with the claimed nucleic acids.

Likewise, none of the potential promoters, flanking sequences, mutations, or genes that are to be identified as final products resulting from processes involving the claimed nucleic acid have asserted or identified specific and substantial utilities. The research contemplated by the applicants to characterize potential promoters, flanking sequences, mutations, and genes does not constitute a specific and substantial utility.

Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds. Neither the specification as filed nor any prior art of record discloses or suggests any property or activity for the claimed polynucleotides such that another non-asserted utility would be well established for the compounds.

The instant situation is analogous to that which was addressed in *Brenner v. Manson*, 148 USPQ 689 (1966) and *In re Fisher*, 76 USPQ2d 1225 (CAFC 2005). In *Brenner v. Manson*, the court held that 35 U.S.C. 101 requires that an invention must have either an immediately apparent or fully disclosed "real world" utility.

"The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial

utility…[u]nless and until a process is refined and developed to this point where specific benefit exists in currently available form there is insufficient justification for permitting an appellant to engross what may prove to be a broad field…a patent is not a hunting license…[I]t is not a reward for the search, but compensation for its successful conclusion."

In Fisher, the court held that Fisher's asserted uses for ESTs did not qualify as either specific or substantial utilities under *Brenner v. Manson*.

Claim Rejections - 35 USC § 112

5. Claims 1-2, 4, 6-12 and 14 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Response to Arguments

6. The response traverses the rejections under 35 USC 101 and 112/first paragraph enablement for the same reasons. The response asserts that one use of the elected SEQ ID NO: 11 can be shown by a BLASTN analysis, which is a well-known and conventional technique that can be used to obtain information on nucleic acid sequences. This argument has been thoroughly reviewed but was not found persuasive. Although the specification at page 5, explains how a BLASTN search is performed, the specification provides no specific or substantial utility for SEQ ID NO: 11.

The response asserts that a BLASTX analysis of the protein sequence encoded by SEQ ID NO: 11 has highly significant correlations with the sequence of acyl ACP desaturase from a variety of plants and that one of ordinary skill in the art would recognize that the BLASTX analysis demonstrates that SEQ ID NO: 11 has a specific, substantial and credible utility that is specific to it, while US Patent 5,723,595 indicates that acyl ACP desaturases can be used to

manipulate the fatty acid content of plants and a skilled artisan would recognize the utility of SEQ ID NO: 11. This argument has been thoroughly reviewed but was not found persuasive. In previous responses (11/3/2006, 8/8/2007) Applicants asserted that based on BLAST analysis, SEQ ID NO: 11 correlated to storage proteins in plants and are important in human nutrition and more specifically "The confirmatory BLASTN analysis provides additional support for Applicants' assertion that SEQ ID NO: 11 is reasonably correlated to a wheat storage protein-encoding sequence. A 95 percent identity over 92 percent of the length of a storage protein sequence obtained from *Triticum aestivum* is, without a doubt, a reasonable correlation" (response dated 2/21/2008, page 12). Now, in the present response, Applicants assert that BLAST analysis shows highly significant correlations with the sequence of acyl ACP desaturase from a variety of plants. However, as evidenced by the citations provided by applicants with regard to storage proteins vs ACP desaturases, these proteins are structurally and functionally different. It is not known if SEQ ID NO: 11 encode a storage protein or a ACP desaturase, and the specification provides no disclosure as to whether SEQ ID NO: 11 encodes a protein, which protein it encodes, if a protein encoded by SEQ ID NO: 11 is expressed and if so where, or a function for a protein encoded by SEQ ID NO: 11. Any nucleic acid sequence, including any sequence from a wheat plant, can be used in a BLAST analysis. The specification merely discloses that the skilled artisan may perform a BLASTN search on the sequences disclosed to then determine if a specific and substantial utility exist for the sequences in the specification. This is not a specific and substantial utility but rather an invitation for the artisan to then determine whether a specific and substantial utility exists.

The specification at the time the invention was filed only generally discloses that the SEQ ID NOS can have high homology to wheat proteins but does not teach what these wheat proteins are, how they function, or whether any homology less than 100% identity would provide for a predictable correlation between the structure and function of the putative unknown, undisclosed homologue. However, In *Brenner v. Manson*, the court held that : "...a patent is not a hunting license...[I]t is not a reward for the search, but compensation for its successful conclusion." Here, the specification does not teach whether SEQ ID NO: 11 encodes a protein nor does it teach expression analysis or a function for a protein encoded by SEQ ID NO: 11, or homology to storage proteins or ACP desaturases. The specification provides no teaching of any immediate benefit to the public regarding the sequence of SEQ ID NO: 11. The fact that the responses have asserted "correlations" to structurally and functionally different proteins using BLAST analysis, and the specification is entirely silent as to whether SEQ ID NO: 11 encodes a protein, or expression analysis or a function for a protein encoded by SEQ ID NO: 11, whether it functions as a storage protein or ACP desaturase illustrates that no immediate benefit has been disclosed by the specification at the time the invention was filed nor was the function of SEQ ID NO: 11 well established in the art at the time the invention was filed. For these reasons and the reasons already made of record, the rejections are maintained.

7. Claims 2, 8 and 14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a substantially purified nucleic acid molecule which comprises SEQ ID NO: 11 and encodes a wheat protein (claim 2), as well as a substantially purified nucleic acid molecule comprising a fragment from about 50 to about 100 nucleotide residues which exhibit complete complementarity to SEQ ID NO: 11 and comprises a region which has a single nucleotide polymorphism (claim 8).

The specification teaches the sequence of SEQ ID NO: 11. Claim 1 and SEQ ID NO: 11, per se, meets the written description requirement of 35 USC 112, first paragraph. However, SEQ ID NO: 11 is an EST, and is less than a full length open reading frame. It appears to be a fragment of a larger protein since it was isolated from a Triticum aestivum cDNA library. The specification does not teach the function of the larger protein encoded by SEQ ID NO: 11, and provides no description of the remainder of the coding sequence of which SEQ ID NO: 11 appears to be a part of. It is not clear what peptide is encoded by SEQ ID NO: 11, as the specification does not teach, for example, if nucleotide position #1 of SEQ ID NO: 11 is the first nucleotide in a codon, or the second or third.

Due to the open language "comprising", Claim 1 encompasses a genus of nucleic acid molecules which comprise the sequence of SEQ ID NO: 1, allowing for any combination of nucleotides on either side of SEQ ID NO: 1. Although claim 1 meets the written description requirement as one of skill in the art could determine which sequences comprise SEQ ID NO: 1 vs those that do not, and could therefore distinguish members of the claimed genus, Claim 2 is directed to a subgenus of nucleic acids of claim 1 and is directed to a nucleic acid which encodes

a wheat protein, or fragment of a wheat protein. However, the specification does not teach what structural requirements of the genus of nucleic acids comprising SEQ ID NO: 11 make a sequence a wheat protein vs that of another plant, or organism. It is not clear which structural aspects of a nucleic acid comprising SEQ ID NO: 11, distinguish it from "non wheat" proteins. Accordingly, it is not representative of the genus of sequences encompassed by the claims.

Claim 8 is drawn to a nucleic acid molecule which comprises at least portion of SEQ ID NO: 11 and a region comprising at least one single nucleotide polymorphism (SNP). Accordingly, claim 8 is directed to allelic variants of SEQ ID NO: 11. Each member of the claimed genus does not contain the same structural feature. The specification teaches that SNPs are single base changes in genomic DNA, that occur at greater frequency and are spaced with greater uniformity throughout the genome and teaches that they can be characterized using conventional techniques for detecting mutations in DNA, however, the specification does not disclose any sequences with a single nucleotide polymorphism in SEQ ID NO: 11 nor any allelic variants of SEQ ID NO: 11. There is no description of the mutational sites that exist in nature nor a description of how the structure of SEQ ID NO: 11 relates to the structure of different alleles. The general knowledge in the art as to how to detect nucleotide differences in DNA does not provide any indication of how the structure of one allelic sequence is representative of other unknown allelic sequences. The common attributes of the genus are not described nor are the identifying attributes of individual sequences with a SNP. The nature of SNP containing sequences is that they are variants and the structure and function of one does not provide guidance as to the structure and function of others. This large variable genus of nucleic acid molecules is not represented by the single sequence of SEQ ID NO: 11. There is no structure

function correlation between the single disclosed species, and the large genus of mutants and allelic variants, encompassed by the broadly claimed invention.

While one could argue that the claimed genus of polynucleotides is adequately described since one can identify these polynucleotides by sequence comparison using the polypeptide/polynucleotide structures disclosed in the instant application or the prior art, the state of the art teaches that sequence comparison alone is not a reliable indicator of a protein's function. For example, Skolnick (Skolnick and Fetrow, TIBTECH, January 2000, vol. 18, pp 34-39) teaches (p. 35, "Box 1") that a common protein characteristic that makes functional analysis based only on homology especially difficult is the tendency of proteins to be multifunctional. Skolnick teaches that for example, lactate dehydrogenase binds NAD, substrate, and zinc and performs a redox reaction and that each of these occurs at different functional sites that are in close proximity and the combination of all four sites creates the fully functional proteins. Skolnick teaches that because the sequence identity between subfamilies is so high, standard sequence similarity methods could easily misclassify new sequences as members of the wrong subfamily if the functional sites are not carefully considered.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116.)

The skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993), and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

Newly added claim 14 recites "fragment of a protein having greater than 30 amino acids". The specification has been thoroughly reviewed but does not provide support for such and thus the amendment appears to have introduced new matter into the claimed invention.

Response to arguments

8. The response traverses the rejection. With regard to claim 2, the response asserts that given Applicants' disclosure, a skilled artisan would recognize that Applicants have provided both a precise definition of the genus of nucleic acids encompassed by claim 2 and a structural feature common to the genus, SEQ ID NO: 11. This argument has been thoroughly reviewed but was not found persuasive. While the sequence of SEQ ID NO: 11 is common to the genus claimed in claim 2, claim 2 is broadly drawn to sequences comprising SEQ ID NO: 11 and not all sequences comprising SEQ ID NO: 11 necessarily encode a wheat protein as the term "comprising" encompasses any combination of nucleotides on either side of SEQ ID NO: 11. If they did, then claim 2 would not further limit claim 1. Accordingly, additional criteria are required to define the genus of nucleic acids in claim 2. However, the specification provides no definition to distinguish a "wheat protein" from a "non wheat" protein, and thus does not provide any relevant identifying characteristics to distinguish the subgenus of nucleic acids encompassed by claim 2, from non members. Applicants arguments that a BLAST X search shows that nucleic acid molecules falling within the scope of the claim 2 are readily identifiable is not found persuasive because not all possible sequences comprising SEQ ID NO: 11 are necessarily so described in the art. Accordingly, applicants' arguments regarding the test set forth in Eli Lilly an Co is not found persuasive as the presence of SEQ ID NO: 11 does not distinguish members of the claimed genus from non members as discussed above.

With regard to claim 8, the response asserts that having provided the sequence of SEQ ID NO: 11, Applicants have provided a precise definition and a structural feature in common to the nucleic acid molecules encompassed by claim 8 and that the specification teaches methods of

detecting SNPs at pages 22-23. This argument has been thoroughly reviewed but was not found persuasive as the genus of nucleic acid molecules of claim 8 are variants of SEQ ID NO: 11, and therefore the members of the genus do not contain the entire sequence of SEQ ID NO: 11. Not all sequences that contain a nucleotide difference with SEQ ID NO: 11 are "SNP" containing sequences. The specification does not disclose any SNPs in SEQ ID NO: 11 or any allelic variants of SEQ ID NO: 11. There is no description of the mutational sites that exist in nature nor a description of how the structure of SEQ ID NO: 11 relates to the structure of different alleles. The general knowledge in the art as to how to detect nucleotide differences in DNA does not provide any indication of how the structure of one allelic sequence is representative of other unknown allelic sequences. The common attributes of the genus are not described nor are the identifying attributes of individual sequences with a SNP. Applicants' argument that the ordinary artisan would be able to distinguish a SNP in SEQ ID NO: 11 or a portion thereof by direct comparison with the sequence of claim 8 is not found persuasive because all sequences that contain a different nucleotide compared to SEQ ID NO: 11 are not necessarily SNP containing sequences.

For these reasons and the reasons already made of record, the rejection is maintained.

Conclusion

9. No claims are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Sitton whose telephone number is (571) 272-0752. The examiner can normally be reached Monday, Tuesday and Thursday from 9:00 AM to 3:00 PM.

NOTE: The examiner will be on Maternity Leave May through August 2009.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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/Jehanne Sitton/
Primary Examiner
Art Unit 1634